

**Disclaimer:** It should be noted that statements made in this consultant report are the expression of individual views and opinions and do not necessarily reflect the facts or agency policy or guidance, and cannot be construed as official representations of (as examples) statutes or regulations.

## External Consultant #4 Report

### Background:

This assessment focuses only on the scientific component of this activity. Moreover it is a review of the processes that are used and the viewpoints of scientists who are engaged within, and outside of the FDA. No chemical assessments were reviewed. In preparing this assessment, I have reviewed the following materials that were provided to me on April 30, 2013:

- (1) "FDA Foods Program Review of Chemical Safety Capacity and Management: Results of Chemical Safety Assessment Personnel Interviews", prepared for CFSAN/FDA by Versar Inc., February 22, 2013
- (2) "FDA Foods Program Review of Chemical Safety Capacity and Management: Results of External Interviews", prepared for FDA/CFSAN by Versar, Inc. April 23, 2013.
- (3) "Report on FDA CFSAN's Redbook", authored by (b) (6), undated.
- (4) "Results from the Listening Session that CFSAN/CVM/OFVD Conducted as Part of the Chemical Safety Assessment Review", author unknown, undated.

Additionally, I attended a meeting on May 31, 2013 in which the above documents were discussed with staff from Versar, FDA leadership and other consultants to Versar on this project, namely, (b) (6) and (b) (6) - (b) (6). At that meeting Versar provided two additional documents:

- (1) "FDA Chemical Safety Program Review Results of Interviews" (PowerPoint presentation)
- (2) "FDA Foods Program Review of Chemical Safety Capacity & Management: Report Skeleton" (individual interview reports)

Finally, in response to some issues that I raised at the May 31 meeting I had an additional phone meeting with Versar staff, on June 11, 2013.

### ***Survey Methodology:***

The FDA did an excellent job with identifying and securing participation from scientists in CFSAN and CVM who currently are involved with regulatory reviews of the safety of chemicals in the food supply and in veterinary medicines. The survey had decent response rates and it is probable that the results can be generalized to the subset of CFSAN and CVM scientists who were selected for study on the basis of their role in conducting assessments. Of note is that there was a wide range of time employed at the FDA and some responses that suggested that there were issues with retention of scientific personnel in these areas. Although "FDA Alumni" were interviewed there was no systematic approach to interviewing recently departed

alumni, which might have provided a more representative picture of the experience of scientists working in the CFSAN/DVM arena. The interviews of FDA alumni and of other federal agency managers were interesting and helped to corroborate some of the findings from interviewing the FDA scientists. The interview of one academic scientist did not provide much information and given the problem with trying to interpret the responses of a single individual I have elected to ignore it for the rest of this report.

Recommendation 1: FDA management should systematically conduct “exit interviews” for all scientists who depart from the FDA to determine the reasons for their departures and to spot problems that need intervention.

Recommendation 2: If the FVMP management is concerned about the perceptions/reputation of their scientists among academic scientists it could consider a separate process, perhaps working through affiliated professional associations like the Society for Toxicology, the International Society for Environmental Epidemiology, and a subsection of the American Chemical Society, perhaps the Division of Agricultural and Food Chemistry.

#### ***FDA FVMP Chemical Safety Scientist Job Satisfaction:***

The interviews elicited a wide variety of viewpoints from FDA scientists. It is of concern that only a bare majority (54%) felt positive about FVMP, that it is a good place to work, that their work makes a difference. The numbers who are neutral (29%) and negative (17%) overall are unusually high among scientific professionals, and of even more concern when considering that dissatisfaction seems to be concentrated in CFSAN generally and among Chemical Hazards Assessment Team (CHAT) and Office of Cosmetics and Colors (OCAC) employees specifically.

Of potential interest in terms of toxicologists is the result of a recent (2009) Society of Toxicology survey of its membership which identified the following issues related to job satisfaction of their members generally: *flexibility/adaptation* (balancing work & family) -- 31% very important, 29% somewhat important; *career progression throughout life* -- 54% very important, 34% somewhat important; *career progression and geographic mobility* -- 35% very important, 43% somewhat important; and *retirement planning, health care, long-term care* -- 29% very important, 30% somewhat important. Some of the survey responses echoed these concerns. In terms of opportunities for advancement many respondents cited the limited opportunity to advance beyond a GS-13, and that there is a perception that policies for promotion and retention as well as opportunities for professional development differ across the agency and according to the assigned supervisor. Several of the FDA alumni who were interviewed very explicitly voiced their concern about FDA's ability to recruit and retain chemical safety scientists currently.

Recommendation 3: FDA FVMP management should seek to identify and address issues within CHAT and OCAC that are contributing to job dissatisfaction. The survey broadly pointed to several issues including: insufficient manpower and scope of expertise; lack of teamwork and peer review; lack of SOPs and guidance; and lack of regulatory authority. I think it would be worth considering the following:

Recommendation 4: Increased attention to prioritization of tasks and matching commitments to levels of manpower including shifting resources, responsibilities and/or deadlines when scientists are asked to take on unanticipated workloads (such as can be created by unanticipated post-market issues). Consider mechanisms to provide contracted expertise in areas that arise infrequently and require specialized knowledge.

Recommendation 5: Consider processes that can break down the “silos” between toxicology and chemistry experts across all of FDA to allow access to subspecialist toxicologists and chemists when highly specialized questions arise, e.g., experts with in-depth knowledge about specific chemicals and/or specific toxicological endpoints and/or specific methodologies. FDA could create such access in a number of ways, e.g., reorganization, creation of “exchanges”, or creation of cross office working group in specific areas or pertaining to specific classes of substances; and/or creation of information libraries that facilitate in information sharing and communication of assessments and analyses across the offices at FDA.

Recommendation 6: Enhance opportunities for communication and collaboration across scientists who are involved in Chemical Assessments. Currently scientists report that communication between the Centers, and with other agencies, leave much to be desired. I very much support some of the recommendations that were put forward in the Versar report, (Section 3.1) especially the need for management buy-in to the idea that time spend in information meetings about chemicals, methodologies, new technologies, emerging issues, regulatory decisions, decision-making processes and results of agency efforts would be time well spent. I also support the idea that regulatory scientists and researchers should have more opportunity to interact.

Recommendation 7: Identify specific areas where the lack of SOPs seems to be a barrier to working effectively. See later comments in this area later.

Recommendation 8: Consider ways to recognize scientific efforts of scientists, e.g., scientists who are at GS-14 levels and below. Management should attempt to recognize the work of teams, especially teams that work across branches and divisions, and not to use awards to recognize achievements of supervisors and managers.

Recommendation 9: Address the need to more consistent availability of resources and time for training and development, including attendance at scientific meetings.

Recommendation 10: Establish and consistently implement flexible workplace policies in FVMP that facilitate and increase times where scientists may work from home, work from a distance, and participate in meetings virtually.

***FDA FVMP Chemical Safety Science:***

The interviews elicited a wide variety of viewpoints from FDA FVMP Chemical Safety scientists. Those responding negatively about FDA science were a much larger percentage than one would wish for, considering the fact that these scientists have self-selected to work at the FDA and presumably have many other options. 33-40% did not feel that FDA's research is adequate in terms of scope, scale and alignment. A number of scientists were aware of updates that are needed to the Red Book, and listed a wide array of areas that they feel need updating. Only 71% of these scientists think that the FDA's peer review process is working as it should. Nearly half find it difficult to coordinate or collaborate across FDA program offices.

FDA Chemical Safety Review scientists mentioned a number of "emerging issues" that many felt need to be address, most notably, novel products (nanotechnology, botanicals and supplements); endocrine disruptors; effects of mixtures and groups of chemicals; post-market review, low dose effects; sensitive populations; genetically engineered organisms; identification and assessment of allergenicity; and how to utilize "Tox 21" methods. In this regard the recent SOT survey of its membership reported seven "important" topics identified by its membership: (1) integration of newer technologies into risk assessment; (2) issues related to genetic variability in humans that impact human risk assessment based on animal studies; (3) participation of toxicologists in translational research and medicine; (4) funding for toxicological research; (5) content of academic training programs—match to future workforce needs; (6) the evolving paradigm of toxicology testing (based on the 2007 NAS report Toxicity Testing in the 21st Century); and (7) gene-environment interactions in humans and animal models. Many of the same issues listed by FDA chemical safety scientists and the SOT survey also were brought forward in the interviews of other agency scientists.

Most of (nearly 80%) of those interviewed recognize opportunities for harmonization of methodologies with other agencies and 30% of respondents were aware of unjustifiable differences between chemical safety assessment methods used by various FDA offices and Centers. About 22-27% did not feel that FDA methods are state of the art. (b) (6) evaluated the Red Book and developed a set of recommendations for updating it. The FDA alumni who were interviewed were generally in agreement with the idea that the Red Book can and should be kept more up to date.

Many of the same issues about the science came through in the interviews of FDA "Alumni" and the three interviews of other agency scientists.

Recommendation 11: Expanding research may not be possible in the current budgetary climate. Currently the CFVM is fostering better communication between regulatory and laboratory scientists. Additional effort to improve communication and coordination between regulatory and research science is needed. At the same time the FDA needs to identify ways to leverage the research that is being funded by others, e.g., the private sector, the NIH, NSF, EPA and USDA.

Recommendation 12: FDA should take the peer review issue to the next level to understand if this problem is across-the-board or concentrated in specific areas. Do managers understand the policy? Are there adequate resources (time and money) to support required peer reviews? Are the results of peer review taken seriously?

Recommendation 13: The FDA FVMP scientists could benefit from collaboration with the SOT and other professional organization, as well as with scientists in other offices at the FDA and in other federal agencies, on issues like integration of new technologies and incorporation of novel endpoints; review of novel products; research priorities; academic training programs; and Tox 21.

Recommendation 14: I concur with (b) (6) recommendations with regard to the Red Book and particularly her advice to keep it focused on the U.S. regulatory program, to expand the information on interpretative guidance, to make better use of existing resources to update guidance and create guidance more frequently, and to play a more active role in Tox 21 with the ultimate goal of replacing or reducing whole animal tests in the long run.

***FDA FVMP Chemical Safety, Relationships with Other Agencies and Entities and Transparency:***

There seemed to be general recognition that coordination and collaboration with other agencies leave much to be desired. At that same time, it appears that in some areas these relationships recently have been improving. It appears that, when invited in, FDA's chemical safety scientists have willingly contributed to efforts like EPA's IRIS prioritization and pesticide registrations. It also appears that engagements that occur at a higher level within FDA (Mike Taylor, the Commissioner's Office) go very well. At the same time a number of impediments were mentioned. The other agencies cited missed opportunities for collaboration, problems with sharing confidential data and a perception that FDA scientists are not open-minded and do not wish to share information. At the same time the FDA FVMP Chemical Safety scientists who were interviewed communicated a fair amount of frustration with the lack of understanding of their science-based policies and FDA's regulatory science.

Recommendation 15: The FVMP needs to develop a proactive approach to bringing the outside in on chemical safety reviews. It may be able to learn from approaches that have been used by other agencies. For example, the EPA Office of Pesticide Programs uses its Pesticide Science Advisory Panel to hold public discussions about

SOPs and the development of new approaches to the evaluation of pesticide data. It brings many of its most contentious and difficult reviews to the SAP in order to obtain feedback from the SAP, as well as members of the public, on complex science policy choices that arise in the case of individual pesticides. In this regard, the FDA needs to make background materials for such presentations available as far in advance of meetings as possible in order to maximize the opportunity to obtain informed input.

Recommendation 16: FVMP Chemical Safety scientists need to be more engaged within the larger community of regulatory scientists and encouraged and rewarded for presenting their work at science association meetings and in journals.

Recommendation 17: The FVMP Chemical Safety scientists need the support of communications experts who are adept at translating the results of science evaluations to plain English. For example (from one of the interviews), stating that a study (b) (5) for evaluation (b) (5) is not clear. If instead the FDA had stated that proper records were not kept, or proper methods for dosing animals were not employed, this would be far clearer explanation for why a study was rejected.

***FDA FVMP Chemical Safety, Ability to Meet its Mission:***

It is of concern that a bare majority of the FDA scientists interviewed, 54%, felt that the Centers have “the scope and depth of expertise they need to fulfill their chemical safety regulatory obligations and meet today’s (and future) chemical safety challenges.” The major problem seems to be depth of expertise with only 37% having responded that they have adequate depth, and most of the concern focused on CFSAN. This may have to do with the fragmentation of these groups within smaller offices and teams and the lack of adequate mechanisms to share expertise among these small groups. In this regard, see recommendations 4, 5, and 6 above.

Recommendation 18: CFSAN needs to take stock of its depth of toxicological expertise and whether they truly have a critical mass to fulfill their regulatory obligations, and need to change how they manage these resources; if they lack a critical mass; or (most likely) if they need to both evolve a new management approach and bring onboard more personnel (or contracting resources) to expand the depth of expertise.

In closing, it has been a pleasure to work with you, the other consultants and the dedicated staff at the FDA who launched this effort to review the FDA Chemical Safety Program. I hope that my observations and recommendations are helpful.